



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/242,103 02/08/99 ASIUS

J 0198/00047

EXAMINER

QM12/0801

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PO BOX 19088
WASHINGTON DC 20036

ART UNIT

PAPER NUMBER

3738
DATE MAILED:

08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/242,103

Applicant(s)

ASIUS ET AL.

Examiner

Choon P. Koh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 5/18/01 have been fully considered but they are not persuasive.
2. It is noted that claims 21-36 are presented in the amendment instead of claims 21-30 as Applicants indicated.
3. Claims 21-36 differ from claims 1-20 only in the exclusion of poly- ϵ -caprolactone from the group of polymers which are used for forming microparticles. The newly added claims are directed to **microspheres or microparticles** consisting of at least one polymer chosen from the group consisting of **lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid copolymers**.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 21-36 are rejected under 35 U.S.C. 103(a) as obvious over Beisang et al (Aesth. Plast. Surg., 1992) in view of Scopelianos et al (5,599,852) or further in view of any one of Tom et al (Biotechnol. Prog., 1991) or Perraud (FR 2778847) and for various of the claims, further in view of either Ron, Ersek or Wallace for the reasons set forth in the previous office action of Paper No. 8, pages 2-7.

6. With respect to Scopelianos, the Applicants argue that Scopelianos reference is disqualified because Scopelianos teaches microparticles comprising poly-ε-caprolactone and new claim 21, from which the remaining claims depend, recites the composition of the microparticles as “consisting of” **lactic acid polymers, glycolic acid polymers, and lactic acid-glycolic acid copolymers** which exclude poly-ε-caprolactone .
7. The examiner does not agree with the Applicants’ interpretation of the disclosure of the Scopelianos reference.
8. While the Scopelianos et al reference teaches the use of poly-ε-caprolactone as a polymer component in the most preferred liquid polymers or copolymers that possess the rheologic properties of microdispersions suitable for injectable implant for soft tissue repair and augmentation, the same reference also teaches lactic acid polymers as microparticles in an injectable implant as set forth in claim 21 (col. 18, Example 24).
9. Therefore, Scopelianos et al reference is not disqualified as the Applicants argued.
10. Perraud (FR 2778847) teaches resorbable injectable implant comprising microspheres made from PGLA or PLA containing drugs which microspheres are in a suspension of a gel comprising hyaluronic acid.
11. Tom et al (Biotechnol. Prog., 1991) teaches bioerodible polymeric microspheres and microparticles formed from lactic acid polymers, e.g. poly (L-lactic acid)(L-PLA), poly (DL-lactic acid)(DL-PLA) and glycolic acid polymers, e.g. poly (glycolic acid) (PGA).

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12. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to have used other well known biocompatible, bioabsorbable polymers, including those taught by Tom et al or Perraud in forming microspheres according to the method taught by Scopelianos et al and use the microspheres according to the method taught by Beisang et al with a reasonable expectation of success in obtaining an injectable implant having desired properties.
13. With respect to Ron et al (U.S. Patent No. 5,597,897), Applicants argue that the reference does not teach an injectable gel and/or microspheres that exclude proteins of animal origin, e.g. osteogenic proteins.
14. However, Ron et al reference was used for its teaching of CMC or HPMC as well known gel-forming carrier for microspheres formed of lactic acid polymers, the glycolic acid polymers or the lactic co-glycolic acid polymers.
15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Conston et al (WO 9911196) teaches an injectable and flowable material for tissue repair comprising microspheres, wherein active components, such as drugs may be incorporated into the material to provide local delivery of a therapeutic agent.

Hubbard (WO9315721) teaches a biocompatible material for soft tissue augmentation comprising CMC as a gel carrier for microparticles.

DeWijn (4,093,576) teaches various gelling agents, including CMC.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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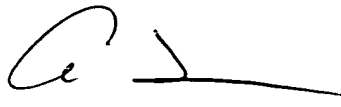
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Choon P. Koh whose telephone number is 703-305-1232. The examiner can normally be reached on Mon-Fri. 6:30 - 4 pm; alternate Fridays 6:30-3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Choon P. Koh
July 30, 2001


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700